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MICROCOIL CONSTRUCTION**BACKGROUND OF THE INVENTION****Field of the Invention**

This invention relates to microcoils and their construction. Specifically, this
10 invention relates to microcoils for use in medical devices used to obtain a magnetic
resonance image of a region within a natural organism or patient (such as within a
human) or elsewhere.

Background of the Invention

15 The use of magnetic resonance medical devices provides enhanced imaging
within the region of interest and can be used for various internal procedures including
targeted drug delivery. The term microcoil or MR microcoil is used to denote a magnetic
resonance device used for imaging internally from a patient. This term is in contrast to
MR coils that are conventionally used externally to the body for MR imaging purposes.
20 A microcoil may contain one winding of electrical conductor, or multiple windings that
are spaced a distance apart from each other. Typically multiple windings are joined
together at a predetermined spacing with the planes of the windings parallel to each other.

The MR microcoil may be mounted at the tip of a catheter or other insertion
device used to probe the interior of a body. The combination of the microcoil mounted
25 on another device provides quick and direct access to the region where imaging is
required. Medical procedures such as image-guided and minimal access surgery,
performed within small regions of a patient's anatomy, demand the ability to visualize the
internal terrain and/or the procedure being performed by the surgeon. While alternative
methods, including x-ray imaging and fiber optic viewing offer possible alternative
30 means of performing the visualization of terrain and the location of physical secondary
devices, magnetic resonance imaging methods are a particularly convenient means of
doing this, especially given the highly localized nature of the procedures being
performed.

As with any manufactured device, new methods of manufacturing components are
35 always being pursued to enhance performance and lower manufacturing costs.

5 Conventionally, microcoils are manufactured by hand winding of an electrical conductor around a mandrel, or alternatively machine winding an electrical conductor around a mandrel. The resulting winding may have to be removed from the mandrel, and the leads for each end of the winding must be isolated. Additionally, where multiple windings are joined together in a device, the ends from multiple windings need to be connected.

10 Handling windings in the manufacturing process can cause damage to the fragile windings resulting in manufacturing yield loss. The trend of smaller devices only increases this problem. With minimally invasive surgical procedures, the electrical conductor diameters used must be increasingly smaller to provide smaller coils. These coils are more easily damaged.

15 In manufacturing microcoils, there are also dimensional control variations within a single winding, and between windings. The diameter of the an electrical conductor used in a single winding may vary and affect the electrical characteristics of the resulting winding. Similarly, the insulating coating around the electrical conductor may vary in thickness and affect the electrical properties of the winding.

20 From one winding to another, variations in electrical conductor diameter and coating thickness are still a manufacturing variable. In addition, the number of turns from one winding to the next must be controlled by measuring the length of electrical conductor used in each winding. Also, the distance between windings in a microcoil containing multiple windings must be controlled by carefully joining the ends of a
25 conventional winding at a measured distance.

While these conventional approaches to the manufacture of windings and microcoils result in functioning microcoils, the process is time consuming with several steps. Manufacturing yield is a problem due to the handling necessary in the conventional process, and consistent quality control is difficult.

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SUMMARY OF THE INVENTION

What is needed is a microcoil that can be manufactured more easily and which results in a more uniform microcoil with more consistent quality. What is also needed is a microcoil made by attaching a conductor onto an insulating film and configuring the
35 film to form a winding or multiple windings. The manufacturing process of the microcoil

5 requires minimal processing steps and minimal exposure to handling damage during processing. The process of manufacturing the microcoil is also conducive to tight quality control standards yet it is easily adapted to accommodate product design changes. The novel manufacturing process is capable of producing a novel microcoil that is extremely small and inexpensive, with a high manufacturing yield.

10 Microcoils produced by this process could be round or have other shapes depending on the mandrel or form that the film wraps around. A microcoil can be formed by soldering an end of the film to the mandrel and turning it to wrap the film into a winding. Multiple windings could also be included in one microcoil to make a series of connected windings.

15 In a further embodiment of the invention, the conductor is deposited as a trace onto the film using lithography and sputtering deposition techniques. The shape of the resulting microcoils is easily controlled by changing the mask pattern for the conducting trace deposited on the film. The electrical properties of the trace of conducting material are easily controlled by varying the trace material, and the width/thickness of the trace.

20 The microcoil might be applied with a medical device such as a catheter where the catheter is guided by magnetic resonance imaging using the microcoil. The microcoil might be further combined with other electrical devices nested at least partially inside the coil.

25 BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a top view of a trace unit in a flat condition.

Figure 2 is a sectional view along line 2-2 of the trace unit in a flat condition in figure 1.

Figure 3a is a perspective view of a trace unit and a mandrel.

Figure 3b is a perspective view of a trace unit being rolled onto a mandrel.

30 Figure 4a is a side view of a microcoil.

Figure 4b is a front view of a single winding of a microcoil.

Figure 4c is a sectional view along line 4c-4c of a single winding in figure 4b.

Figure 5 is a perspective view of a microcoil.

Figure 6 is a perspective view of a catheter device.

35 Figure 7 is a close up view of an end of a catheter device.

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DESCRIPTION OF THE INVENTION

A catheter 100 is shown in figure 6, is used to probe areas of interest inside a patient. The distal end 101 of the catheter 100 can be inserted by controls at its proximal end 102. In order to image the area of interest, and potentially steer the distal end 101 of the catheter to the desired location, it is helpful to include an MR microcoil 60 at the distal end 101 of the catheter 100. The microcoil 60 uses magnetic resonance imaging techniques to characterize the tissue in its immediate vicinity. Signals from the microcoil 60 are sent along a length 104 of the catheter 101 through an electrical channel 103 to the proximal end 102 of the catheter where they can be used by the surgeon to indicate where the distal end 101 of the catheter is, and what types of tissue are near the distal end 101.

A microcoil 60 as shown in figure 5 is manufactured by rolling a trace unit 10 as shown in figure 1 in such a way as to form at least one winding 70. A preferred embodiment of the microcoil 60 contains both a first winding 70, and a second winding 75 electrically connected and spaced apart by a joining portion 39. The microcoil 60 and method for forming the microcoil 60 are described in detail below.

Figure 1 shows a trace unit 10 that is comprised of a flexible film 20, a conducting trace 30, and an attaching trace 45. As shown in Figure 2, the flexible film 20 has a thickness 21 and the conducting trace 30 has a thickness 46. In a preferred embodiment, the thickness 21 and the thickness 46 are constant across the trace unit 10, however, the thickness 21 and the thickness 46 may vary in alternate embodiments. The flexible film 20 may have several shapes. It may be continuous, or it may contain openings in the film in areas other than where it supports the conducting trace 30.

Looking again at figure 1, the conducting trace 30 can be further broken down into a first leg 31 having a first leg length 32 and a second leg 33 having a second leg length 34. The first leg 31 has a lead end 41 and a joining end 42, and the second leg 32 also has a lead end 43 and a joining end 44. The first leg 31 and the second leg 33 have a trace width 49, which is uniform throughout the legs in a preferred embodiment.

The first leg 31 and the second leg 33 are substantially parallel to a trace unit axis 11 of the trace unit 10. However, as shown in figure 1, they are not exactly parallel to the

5 trace unit axis 11. The legs 31 and 33 are shown in a preferred embodiment in figure 1 as having a slight curve, with the curve being more pronounced near a joining portion 39. The orientation of the legs 31 and 33 as shown in figure 1 is only one preferred embodiment. One skilled in the art would recognize that several configurations of legs would be possible to form other preferred embodiments without departing from the scope of the invention.

The conducting trace 30 also includes a first lead 35 and a second lead 37, having a first lead length 36 and a second lead length 38, and a first lead width 47, and a second lead width 48. The width of trace elements such as the legs and leads can be varied between elements, and within elements to alter the electrical characteristics of the trace. For example, a lead 35 could be wider than a leg 31, or a leg 31 could have a varying width along its length 32.

The first and second leads 35, 37 are attached to the first and second legs 31 and 33 at the first and second leg lead ends 41 and 43 respectively. The leads 35 and 37 may alternatively be attached elsewhere along the conducting trace 30 without departing from the scope of the invention. Supplemental leads (not shown) may also be electrically connected to the conducting trace to give device feedback or insert device instructions. The two legs 31 and 33 are joined at their respective joining ends 42 and 44 by a joining portion 39 of the conducting trace 30. The joining portion 39 has a length 40.

The trace unit 10 also includes an attaching trace 45 located adjacent to the joining portion 39. The attaching trace 45 is electrically isolated from the conducting trace 30. In a preferred embodiment, the attaching trace 45 is parallel with the joining portion 39 of the trace unit 10. In a preferred embodiment, the attaching portion is also substantially perpendicular to the legs 31 and 33.

The conducting trace 30 is comprised of copper because of its high conductivity and ductility. The ductility allows the copper to be rolled without cracking or breaking or otherwise causing an electrical failure. Any other conducting material that satisfies these conditions would be acceptable. The flexible film is comprised of polyimide because it exhibits good insulating properties and is readily available. It is also flexible, and withstands the deposition process used to attach the conducting trace. Any other flexible insulating material would be acceptable.

5 The conducting trace is attached to the flexible film by using a sheet of conductor, adhesive, and a basic lithography or photolithography technique commonly known in the industry. First a sheet of copper is adhered to the flexible film using a suitable adhesive. A mask layer is then deposited onto the sheet of copper with a positive image of the conducting trace 30 and the attaching trace 45. The flexible film 20 and the mask layer
10 are then exposed to an etching chemical capable of removing copper, which removes the copper in the unmasked regions of the sheet. Once the excess copper is removed from the flexible film 20, the mask layer is removed to leave behind only the flexible film 20, the conducting trace 30, and the attaching trace 45. While this method of attaching the conducting trace 20 and the attaching trace 45 is preferred, it should be noted that any of
15 several methods for attaching, including sputtering, physical vapor deposition, chemical vapor deposition, or mechanical attachment could be used to produce the invention.

In alternative embodiments, additional layers of flexible insulator and areas of conducting material may be attached and deposited onto the flexible film 20. Additional layers of flexible insulator may be used to protect the conducting trace 30, or they may be
20 used to isolate additional areas of conducting material from the conducting trace 30. Additional areas of conducting material may be used to form electrical devices such as capacitors, integral with the trace unit 10.

The trace unit 10 is next prepared for rolling by attaching the trace unit 10 to a mandrel 50 as shown in Figure 3a. The mandrel 50 may be round or square or any of
25 several variations in cross section. The mandrel 50 may also be solid or hollow. The mandrel 50 may be made from any of a number of materials such as plastic or glass or non-magnetic metal. The mandrel 50 may not include magnetic materials due to interference with the magnetic resonance imaging that the coils are designed for in end use. The mandrel 50 may also be made up of more than one material. In this
30 embodiment, the mandrel 50 is a semi-rigid coaxial line that is comprised of silver-plated copper on its outside diameter. The semi-rigid coaxial line is electrically conductive which allows information from the coil to be transmitted back to the user through the coaxial line.

A preferred manufacturing process of the microcoil 60 begins when the trace unit
35 10 is attached to the mandrel 50 by soldering the attaching trace 45 to the outside

5 diameter of the mandrel 50. The attaching trace 45 is soldered such that it is parallel with a longitudinal axis 51 of the mandrel 50. More importantly, the attaching trace 45 and mandrel 50 are oriented such that when rolled, the legs 31 and 33 of the conducting trace 30 form windings 70 and 75 as shown in figure 5. Although a mandrel 50 is used to roll the trace unit 10 in a preferred embodiment, the trace unit 10 may be rolled without using
10 a mandrel 50 without departing from the scope of the invention.

In a preferred manufacturing process, once the trace unit 10 is attached to the mandrel 50, the mandrel is rolled about the longitudinal axis 51 in direction 52 as shown in Figure 3b. In a preferred embodiment, the rolling of the trace unit 10 about the mandrel 50 forms a microcoil 60 comprised of a first winding 70 and a second winding
15 75 as shown in Figure 5, one winding formed from each leg 31 and 33. The joining portion 39 electrically connects the pair of windings 70 and 75. Alternative embodiments could form only one winding, which would not require a joining portion, or several windings could be formed, which would require multiple joining portions.

Design variations of the resulting microcoil 60 are easily accommodated with a preferred manufacturing process. The number of turns in the windings 70 and 75 may be controlled by varying the lengths 32 and 33 of the legs 31 and 33 respectively when forming the conducting trace 30 on the trace unit 10. Alternatively, the diameter 53 of the mandrel 50 that is chosen can be varied to change the resulting number of turns. Nine turns are used for a preferred embodiment.
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As shown in figure 5, a longitudinal winding spacing 61 between windings 70 and 75 in the microcoil 60 is controlled by varying the length 40 of the joining portion or portions 39 when forming the conducting trace 30 on the trace unit 10.
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Figure 4a shows a side view of the microcoil 60. In this side view only the first winding 70 of the microcoil 60 is visible. The first winding 70 is further shown in figures 4b and sectional view 4c of figure 4b. As shown in figure 4c, within a given winding, a radial trace spacing 71 is controlled by selecting or varying the thickness 21 of the flexible insulating film 20. Also, a longitudinal axis trace spacing 72 is controlled by varying the shape and orientation of the legs 31 and 33 on the trace unit 10.
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As shown in figure 3a, the legs 31 and 33 are substantially perpendicular to the longitudinal axis of rolling 51. However, the degree of perpendicularity varies along the
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5 legs 31 and 33. In a preferred embodiment, a given portion of a leg near the attaching trace 45 is less perpendicular to the longitudinal axis of rolling 51 than a portion of a leg proximal from the attaching trace 45. For example, the orientation of a generally linear leg could be varied such that the angle the generally linear leg makes with the longitudinal axis of rolling is more or less than 90 degrees. The shape of a leg could also
10 be varied such that a leg is more linear or more arc shaped. These shape and orientation variations translate into variations of the longitudinal axis trace spacing 72.

Once the rolling of the trace unit 10 is complete, a microcoil 60 has been formed. A temporary retaining band 80 may then be placed around the microcoil 60 to hold its shape during the final placement of the microcoil 60 into its associated medical device.
15 After the leads 35, 37 and possibly supplemental leads have been electrically connected to the medical device, the temporary band 80 may be removed. A more permanent protective oversleeve 90 as shown in figure 7 is then used to protect the microcoil and to hold its shape. If needed, other electrical component such as capacitors (not shown) may be embedded or partially embedded inside the structure of the microcoil 60.

20 As shown in figures 6 and 7, a catheter device 100 is used in a preferred embodiment. The catheter device 100 has a distal end 101 and a proximal end 102. The microcoil 60 is located at the distal end 101 of the catheter. In operation, data from the microcoil travels along the length 104 of the catheter 100 through an electrical channel 103. A continuing electrical channel such as a coaxial line (not shown) transmits the data
25 from the electrical channel 103 to another device such as a monitor device. This device receives information from the microcoil 60 concerning location of the distal end 101, or concerning the nature and condition of the tissue near the distal end 101.

Although specific embodiments have been illustrated and described herein, it will be appreciated by those skilled in the art that any arrangement which is calculated to
30 achieve the same purpose may be substituted for the specific embodiment shown. This application is intended to cover any adaptations or variations of the present invention. It is to be understood that the above description is intended to be illustrative, and not restrictive. The scope of the invention includes any other applications in which the above structures and fabrication methods are used. The scope of the invention should be

- 5 determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

007227-639260